IN THE UNITED STATES DISTRICT COURT FOR THE
MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

RUTH SMITH, Individually and as Widow for the Use and Benefit of Herself and the Next Kin of Richard Smith, Deceased,	)	
Plaintiff,	)	Civil No. 3:05-0444
	)	Judge Aleta A. Trauger
v.	)	(Dist. Of MA No.
	)	1:05-cv-11515PBS)
PFIZER, INC., *et al.*,	)	
Defendants.	)	

DEFENDANTS' RESPONSES TO PLAINTIFF'S OBJECTIONS TO EXPERT WITNESS STATEMENTS FILED BY DEFENDANTS

Pursuant to the Court's Scheduling Order of April 30, 2010, as amended orally due to flood conditions in Nashville, Defendants, Pfizer Inc and Warner-Lambert Company LLC (collectively, "Defendants" or "Pfizer") herein submit their responses to the plaintiff's objections to the expert witness statements filed by defendants on May 12, 2010.

Response to Objections to Dr. Donofrio's Expert Witness Statement	
Objection	Response
4:1	Plaintiff's objection posits, without any basis, that "safe and effective" is a legal phrase that no expert should be permitted to utter in the absence of FDA approval. Dr. Donofrio, a neurologist and pain specialist who has used Neurontin and other medicines to treat neuropathic pain throughout his career, is qualified to opine on the efficacy and safety of Neurontin as a treatment for neuropathic pain. And his report provides extensive, detailed bases for his opinion on the safety and efficacy of Neurontin. Plaintiff's suggestion that no medication can be called "safe and effective" in the absence of FDA approval is frankly absurd; doctors throughout the United States use drugs for uses not approved by FDA (i.e., "off label") each and every day. Under Plaintiff's view, none of those doctors would be able to conclude that the drugs they prescribe for their patients are safe or effective. Plaintiff also seems to suggest that, because Dr. Donofrio is a case-specific expert, he

	can only opine on specific causation. The term "specific" in this instance, however, modifies "case," meaning that the expert is intended to offer opinions on the specific case, as opposed to generic opinions on multiple MDL cases. It does not limit the witness's testimony to the issue of specific causation. Finally, Plaintiff argues that the probative value is outweighed by prejudice. Given that Plaintiff will advance the claim, through her expert Dr. King, among others, that Pfizer promoted Neurontin for use in neuropathic pain despite purported evidence of inefficacy, Dr. Donofrio's opinion that Neurontin is effective is obviously probative. There is no apparent basis, and Plaintiff has offered none, for concluding that the fact would be unduly prejudicial.
5:5-7; 5:7-9	Dr. Donofrio's statements that he never relied on detailing or advertising, and that no sales representative ever promoted off-label use of Neurontin to him, but that he regularly prescribes Neurontin for neuropathic pain, are relevant because they tend to refute Plaintiff's contention, advanced by Dr. King, that all or nearly all off-label Neurontin prescriptions were attributable to improper promotion. Plaintiff provides no reasoning or basis why the admission of this obviously relevant fact would be unduly prejudicial.
5:10-11	Pfizer restates and incorporates by reference its response to Plaintiff's objection to 4:1.
5:22-6:4	Dr. Donofrio's clinical experience using Neurontin to treat neuropathic pain is relevant because it tends to refute Plaintiff's claim that Neurontin is ineffective in treating neuropathic pain. His conclusions are reliable because he, like every other physician, considers a wide range of information, including both clinical studies and his own clinical experience using a medication, in ascertaining drug efficacy. Plaintiff's rhetorical question is about experience with patients experience suicidal ideation while using Neurontin is misguided. Dr. Donofrio's experience treating hundreds of patients with Neurontin, and finding that many of them have experienced relief from pain which is, in Dr. Donofrio's clinical judgment most likely attributable to Neurontin, is not in any way comparable to the question whether a clinician can ascertain whether a thought about suicide in an isolated patient is attributable to the patient's underlying disease or some other factor.
7:10-11	Plaintiff will claim at trial (and has claimed in these very objections) that there is no valid scientific basis for claiming that Neurontin is effective for treatment of neuropathic pain. The fact that European regulatory health authorities have approved Neurontin for treatment of neuropathic pain tends to refute that assertion. The fact is therefore relevant. Plaintiff provides no basis, and there is no evident basis, for concluding that admission of this fact will cause undue prejudice.
8:5-7	Dr. Donofrio is a neurologist and pain specialist who regularly uses Neurontin and other medicines to treat pain, and also regularly reviews and relies upon pharmaceutical warning labeling, among other information, to determine the risks and benefits of

	medications. As such, he is qualified to opine on the adequacy of labeling to apprise a physician of the risks and benefits of Neurontin. Plaintiff's objection concerning timeliness of general causation opinions is a non sequitur, as the objected-to language does not contain any causation opinion. As stated above, Plaintiff's assertion that Dr. Donofrio can only discuss specific causation, because he is a case-specific witness, is groundless. Plaintiff also appears to object to the fact that Dr. Donofrio's testimony on the grounds that it "bolsters" opinions stated by other experts. Plaintiff provides no legal basis for the proposition that "bolstering" is a valid objection to expert testimony, and we are aware of none. Finally, plaintiff once again asserts undue prejudice without any stated basis. In this inadequate warning case, it is very likely that the Plaintiff's experts will opine that the Neurontin label was inadequate, and that the Defendant's experts will opine that it was adequate. Pfizer is unaware of any reason why testimony as to the label's adequacy would be unduly prejudicial. (If the Court finds any validity in this objection, Pfizer submits that Plaintiff's experts should be precluded from opining that the Neurontin label was inadequate, as any such testimony would be unduly prejudicial for precisely the same reasons.)
8:11-13	The fact that Dr. Donofrio has treated many patients with Neurontin, and none of them have reported suicidality, is relevant because it tends to refute Plaintiff's claim that Neurontin substantially increases suicide risk. Plaintiff has presented no reason why this testimony would be unfairly prejudicial, and we are aware of none.
8:14-21	Plaintiff's Rule 702 objection lacks any stated basis, and there is no apparent reason why a neurologist would be unqualified to opine on the effects of a neurological medication. The opinion is not inappropriately duplicative because (1) it is testimony from a specific causation expert with a different background than Pfizer's other experts, and (2) general causation is a necessary and appropriate component of any opinion on to specific causation. As discussed above, Plaintiff's objection to "bolstering" lacks any legal foundation. Finally, Plaintiff presents no support for his Rule 403 argument, and we are aware of no reason why Pfizer's presentation of opinion that there is a lack of reliable scientific evidence that Neurontin causes suicide would be unduly prejudicial. To the extent Plaintiff proposes to stipulate that expert commentary on the question whether Neurontin causes suicide would be unduly prejudicial to either party, Pfizer will consider the entry of such a stipulation.

9:1	Pfizer restates and incorporates by reference its response to Plaintiff's objection to 4:1.
11:4-5	As stated in Dr. Donofrio's Expert Witness Statement at pg. 10, Mr. Smith's statement that he wished he could die because of pain and depression comes directly from Mr. Smith's medical record dated May 2, 2003. In addition, under Federal Rule of Evidence, "[i]f of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence in order for the opinion or inference to be admitted." (FRE 703) Dr. Donofrio is a physician who regularly relies on medical records, and Plaintiff's hearsay objection therefore has no merit. Finally, Plaintiff provides no basis for his argument that admission of this fact would be unduly prejudicial. The fact that Mr. Smith expressed a desire to die because of pain and depression before he ingested Neurontin goes to the very heart of Plaintiff's claims, and its extreme probative value is not outweighed by any prejudice to the Plaintiff.
12:6-10	As noted above, Rule 703 permits an expert to rely on information of a type reasonably relied on in his field. Physicians like Dr. Donofrio regularly and reasonably rely on reports from family members concerning patients' condition and mental state. It is therefore appropriate for Dr. Donofrio to rely on Mr. Smith's daughter's statement, as recorded in a police report, that Mr. Smith expressed suicidal thoughts on March 1, 2004, before he ingested any Neurontin. This second pre-Neurontin statement of suicidal ideation is also of great probative value in determining whether Mr. Smith's suicide was caused by Neurontin, or by the same pain and depression that caused him to express suicidal thoughts before he ever used Neurontin. That probative value is not outweighed by any apparent unfair prejudice, and Plaintiff has stated no basis for a finding of prejudice aside from a bare statement that the evidence will be "prejudicial."
12:18	Pfizer restates and incorporates by reference its responses to Plaintiff's objections to 11:4-5 and 12:6-10.
13:27	Pfizer restates and incorporates by reference its responses to Plaintiff's objections to 11:4-5 and 12:6-10.
15:16-22	Dr. Donofrio's bases for concluding that Neurontin is effective in various types of neuropathic pain at doses ranging from 1800-3600 mg/day are set forth at pages 5-7 of his Expert Witness Statement. As Dr. Donofrio states, Neurontin was approved by FDA for one type of Neuropathic pain, postherpetic neuralgia, and the FDA-approved labeling for Neurontin states that the medication has been shown to be effective at doses ranging from 1800-3600 mg/day. Dr. Donofrio's opinion that Mr. Smith's dose was below the normal effective dose for Neurontin is thus supported by studies evaluating its use in several different types of neuropathic pain, and by FDA's finding

	of efficacy for one particular model of neuropathic pain, postherpetic neuralgia. In addition, this opinion is supported by Dr. Donofrio's own experience using Neurontin in patients for many years. Plaintiff's once again states a boilerplate objection to on the grounds of prejudice. She provides no basis for concluding that this opinion would be unduly prejudicial, and we are aware of none.
Response to Objections to Dr. Donofrio's Slide[sic]/Exhibits	
173-2, p.1	Pfizer restates and incorporates by reference its response to Plaintiff's objection to 4:1.
173-2, p.1	Pfizer restates and incorporates by reference its response to Plaintiff's objection to 8:5-7
	This objection does not identify any document or statement to which it applies. However, based on the substance of the objection, it would appear that Pfizer's response to Plaintiff's objection to 4:1 would be responsive, to the extent Plaintiff intends to apply this objection to a particular statement in Dr. Donofrio's demonstrative slides.
Response to Objections to Robert Gibbons, PhD's Expert Witness Statement	
3:21	Dr. Gibbons is a biostatistician whose work largely focuses on the evaluation of purported suicide risks associated with medicinal compounds. He has published numerous studies evaluating pharmaco-epidemiologic evidence of suicide risk in patients treated with medications, including antidepressants and antiepileptic medicines, in peer-reviewed journals. He is the Director of the Center for Health Statistics, and Professor of Biostatistics, Mathematics, Statistics, Computer Science and Psychiatry at the University of Illinois at Chicago. He has also served on FDA advisory committees convened for the express purpose of determining whether there is a signal of increased suicide risk associated with medicinal compounds. Plaintiff's suggestion that Dr. Gibbons is unqualified to evaluate the existence of a signal for increased suicide risk lacks any reasonable basis. Dr. Gibbons' testimony is not cumulative of the testimony of any other of Pfizer's witnesses. Dr. Gibbons, a biostatistician, offers different opinions, based on different data and analyses, and from a different professional prospective, than any of Pfizer's other witnesses. It should be noted that numerous of Plaintiff's experts offer overlapping opinions (e.g., Drs. Blume and Trimble both discuss mechanism of action and Drs. Trimble and Maris both discuss specific causation.)
5:9	The foundation for Dr. Gibbons' statement is found in Plaintiff's objection, which concedes that FDA stated "this information does <u>not</u> mean that FDA has concluded there is a <u>causal relationship</u> between the drug products and the emerging safety issue." Plaintiff seems to suggest that this statement is contradicted by another sentence in

	FDA's alert, but that sentence, which says that FDA's pooled analysis showed that patients receiving AEDs "had almost twice the risk of suicidal behavior," carefully avoids any implication that AEDs were found to cause that increase. Stated differently, FDA's two statements, read together, clearly indicate that FDA found an association, but not necessarily a causal relationship, between AEDs and suicidality. In any event, Dr. Gibbons, an expert biostatistician, is plainly better qualified to interpret these statistical terms than is Plaintiff's counsel. Plaintiff's counsel's disagreement with Dr. Gibbons' interpretation may be a basis for cross examination, but it certainly does not support exclusion. It should be noted that, in this and many other of Plaintiff's objections to Dr. Gibbons' testimony, Plaintiff appears to deliberately confuse the question whether Dr. Gibbons has stated (i) that evidence does not support the existence of an increased risk, or (ii) affirmatively proves that there is no increased risk. In this instance, Dr. Gibbons stated that FDA's analyses "do not indicate a causal link." Plaintiff protests that FDA's alert "does not state that the FDA has concluded that there is no causal link." But Dr. Gibbons has not claimed that FDA made any such statement. This type of semantic chicanery pervades Plaintiff's objections to Dr. Gibbons' testimony.
5:15	Dr. Gibbons' statement that, in the absence of data from topiramate and lamotrigine, the two AEDs included in FDA's pooled analysis that demonstrated statistically significant increased suicide risk, is based on statistical analysis. As Dr. Gibbons explains in his statement: > I compared the difference between the nine other AEDs against placebo and lamotrigine and topiramate against placebo. This plot shows the rate of suicidality events for patients treated with lamotrigine or topiramate (red bar) compared to placebo (grey bar). This shows that treatment with either lamotrigine or topiramate results in a doubling of the probability of a suicidal thought or behavior. Compare this now to the odds ratio for patients treated with the other nine AEDs (blue bar) compared to placebo (dark grey bar). Here, you see that there is no difference between the other nine drugs and sugar pill. (Gibbons Expert Witness Statement at 7-8.) As such, the statement is not speculative, and is grounded in Dr. Gibbons' own statistical analysis.
6:2	This objection presents another semantic argument in which Plaintiff attempts to invert the burden of proof, and require Dr. Gibbons' testimony to establish the absence of risk, as opposed to commenting on the lack of proof of risk. Dr. Gibbons' statement that FDA's analysis showed no increased risk is completely accurate, and his conclusion that the data show no increased risk is fully consistent with accepted scientific and statistical principles. Stated differently, under the "null hypothesis" applied in all scientific inquiry, the presumption is that, unless the data show an effect, there is none. Dr. Gibbons' testimony merely reflects that, in the absence of any data showing a

	statistically significant increased risk, the reasonable, accepted scientific conclusion is that there is no increased risk. In addition, this is another instance where Dr Gibbons is far more qualified than Plaintiff's counsel to determine the proper interpretation of statistical data. Plaintiff's objection might form the basis of cross examination, but it does not support exclusion. Plaintiff's objection under Rule 403 appears to be an attempt to ensure that the jury is confused in the Plaintiff's favor. Plaintiff apparently seeks to present a presumption that Neurontin causes suicide, and to impose a burden of proof on Pfizer to establish that it does not cause suicide. This is, of course, precisely the opposite of the real burden of proof in this case. Plaintiff is required to prove that Neurontin does cause suicide, and the jury will not be improperly confused by Dr. Gibbons' testimony that the scientific evidence does not meet that burden.
6:19	Pfizer restates and incorporates by reference its response to Plaintiff's objection to 6:2
8:7	Pfizer restates and incorporates by reference its response to Plaintiff's objection to 5:15.
8:16 (note that Plaintiff states two objections to this line.)	As stated above, Dr. Gibbons' education and experience make him uniquely qualified to testify about FDA's analysis of suicidality data and its implications for Neurontin. Plaintiff's objection that Dr. Gibbons lacks expertise is without merit. Plaintiff's objection that these opinions are not contained in Dr. Gibbons' report also is unfounded. Dr. Gibbons' opinions concerning FDA's exclusion of trials without suicide events are stated in several of his opinions. (*See*, *e.g.*, 1/5/10 Rpt. at 2; 3/19/09 Rpt. at 2.) As for Plaintiff's Rule 403 objection, Plaintiff will undoubtedly argue that Neurontin is not a safe drug, and in fairness Pfizer must be permitted to argue that it is safe. To the extent that Plaintiff will agree to stipulate that commentary on the safety of Neurontin by any witness is unfairly prejudicial, Pfizer will agree to withdraw the subject statement.
9:19	Pfizer restates and incorporates by reference its response to Plaintiff's objection to 6:2
9:21	Dr. Gibbons' qualifications to evaluate the risk of suicidality in medications, and to interpret the results of statistical analyses, are discussed above. For the same reasons, Dr. Gibbons is qualified to opine whether the results of FDA's analysis are or are not generally consistent. The foundation for this statement is provided in the sentence to which Plaintiff objects, and in Dr. Gibbons' discussion of the large inconsistencies in the findings of FDA's analysis, for example at page 7 of his Expert Witness Statement.
10:11	This objection does not present any plausible legal argument for exclusion. Rather, Plaintiff's counsel simply states that he does not agree with Dr. Gibbons' interpretation of the statistical results of FDA's analysis. And Plaintiff's counsel is completely wrong in suggesting that the presence or absence of confidence intervals affects the

	comparability of FDA's risk estimates with batting averages. In fact, one could easily calculate confidence intervals for batting averages. This is another instance where Dr. Gibbons' qualifications in the interpretation of statistics far exceed Plaintiff's counsel's, and where counsel's disagreement provides potential cross examination, but no grounds for exclusion.
10:21	Pfizer restates and incorporates by reference its response to Plaintiff's objection to 6:2
11:13	This objection is apparently based on a misunderstanding of Dr. Gibbons' testimony. Dr. Gibbons does not opine that the inclusion of topiramate in all analyses is "unfortunate" because topiramate is or is not GABAergic, but because topiramate "had the most events" and (as Dr. Gibbons states in the very next sentence) "[t]his makes any analysis of whether there is difference in risk profiles among the different classes of drugs problematic." Dr. Gibbons does not state an opinion on pharmacology, but on statistics. He opines that it is unfortunate topiramate was included in all groups because its inclusion makes statistical comparison difficult. This statement is obviously within Dr. Gibbons' expertise, and is entirely appropriate.
14:10	Dr. Gibbons states in the sentence at issue that the *Archives of General Psychiatry*, which published Dr. Gibbons' study on AEDs and suicide, concluded that the study was reliable and of scientific importance. Peer-reviewed medical journals accept articles for publications only if they are found, through the peer-reviewed process, to be reliable and scientifically important. Dr. Gibbons' statement merely reflects the obvious implication that, because his article was accepted for publication, the journal and its peer reviewers found the article was reliable and scientifically important.
17:5	Dr. Gibbons' statement that the data show that AEDs do not increase suicide risk is appropriate, and grounded in reliable science, for the reasons stated in Pfizer response to Plaintiff's objection to 6:2. Plaintiff's objections to Dr. Gibbons' statements about a potential protective effect attack a straw man. Plaintiff pretends that Dr. Gibbons has opined that AEDs are certainly protective for suicidality, and then objects to that made-up opinion by noting that there are other potential explanations for the decrease in suicidality Dr. Gibbons' study found in AED-exposed patients. In reality, Dr. Gibbons has stated merely that "if anything, there <u>may</u> be a reduced risk for suicide attempt in these patients. That is, there <u>may</u> be a protective effect of AEDs for suicide attempt." Dr. Gibbons's use of the word "may" appropriately states that the evidence establishes a possible, but not certain, reduction in suicide risk in AED-exposed patients. Plaintiff also objects on the grounds that, according to Plaintiff's counsel, Dr. Gibbons did not conduct his study properly. It is notable, in this regard, that Dr. Gibbons' paper was accepted and published by a peer-reviewed medical journal. In this instance, Plaintiff's objection is based on counsel's bald disagreement with not only Dr. Gibbons, but the Archives of General Psychiatry.

	As for Plaintiff's Rule 403 objection, because Dr. Gibbons has accurately stated exactly what the data show, there is no risk that the jury will be confused by his testimony.
17:7	Pfizer restates and incorporates by reference its response to Plaintiff's objection to 17:5. As for Plaintiff's contention that Dr. Gibbons lacks expertise to comment on bipolar patients' risk for suicide, the statement quoted by Plaintiff clearly notes that "[p]ublished studies show that patients with bipolar disorder have the highest risk of suicide behavior out of all psychiatric disorders." Dr. Gibbons' testimony is based on this literature and, as a highly-qualified biostatistician with extensive experience not only interpreting, but also conducting, studies evaluating suicide risk, he is more than qualified to rely on and interpret this scientific evidence.
18:5	This objection presents no legal argument for exclusion, but merely Plaintiff's counsel's bald assertion that counsel disagrees with the statistical adjustments performed by Dr. Gibbons. This is yet another instance where counsel's disagreement may provide a basis for cross examination, but does not present any basis for precluding a highly-qualified biostatistician from presenting the results of his study. Moreover, Plaintiff again attacks a straw man; Plaintiff complains that Dr. Gibbons did not actually obtain data for medicines other than antidepressants, antipsychotics, and other antiepileptics, but Dr. Gibbons has not stated in his Expert Witness Statement that he adjusted for additional drugs. Rather, the statement clearly indicates that he adjusted for "antidepressants, antipsychotics, and other antiepileptics." (Gibbons Witness Statement at 18.) Plaintiff's claim that the method by which Dr. Gibbons performed his statistical adjustments renders his opinion unreliable (i) is untimely, as the deadline for filing of Daubert motions has long passed, and (ii) totally unsupported.
18:13	This objection represents another misunderstanding, if not misrepresentation, of Dr. Gibbons' testimony. The referenced table (which is not identified in Plaintiff's objection, but which apparently is Table 2 of Dr. Gibbons' 1/5/10 report) lists suicide attempt rates for two different groups of patients. First, it lists the rates in patients using other (concomitant) medications. Those patients' results are potentially confounded by the presence of other medicines, and they are likely to be the most severely ill patients (as they treated with multiple medications), and therefore at highest risk for suicide attempt. Plaintiff's objection refers the rates listed in Table 2 for patients using concomitant medication, but does not mention that the table states the rate for "Gabapentin Monotherapy" patients (that is, patients who are not treated with additional medications) on the very next line of the table. The rates listed for those patients are precisely the same as the one in Dr. Gibbons' Expert Witness Statement, and they are also discussed at paragraph 18 of the 1/5/10 report. (*See* Page 11 and Table 2 of 1/5/10 Gibbons Report) It is possible that Plaintiff's counsel disagrees that the rates for monotherapy patients

	listed in Table 2 and discussed at paragraph 18 of Dr. Gibbons 1/5/10 report are the most relevant rates for evaluating Neurontin's suicide risk. If that is the case, Plaintiff's counsel is free to inquire into the issue on cross examination. In any event, Dr. Gibbons' testimony is 100% consistent with the portion of Table 2 that Plaintiff misleadingly omitted from this objection.
18:19	Pfizer restates and incorporates by reference its response to Plaintiff's objection to 17:5.
19:17	Pfizer restates and incorporates by reference its response to Plaintiff's objection to 17:5.
19:19	Pfizer restates and incorporates by reference its response to Plaintiff's objection to 17:5. The basis for Dr. Gibbons' statements regarding suicide risk in bipolar patients is discussed in Pfizer's response to Plaintiff's objection to 17:7.
20:4	Pfizer restates and incorporates by reference its response to Plaintiff's objection to 6:2.
20:6	Pfizer restates and incorporates by reference its response to Plaintiff's objection to 17:5.
20:9	Pfizer restates and incorporates by reference its response to Plaintiff's objection to 3:21.
Slide 18	Pfizer withdraws this slide, which was mistakenly included in the set disclosed to Plaintiff.

	Response to Objections to Dr. Grabowski's Expert Witness Statement
Objection	***Response***
To Entirety of Dr. Grabowski's Testimony under FRE 401, 403, 608, 702-04	• Plaintiff's Rule 401 objections are not well taken. Dr. Grabowski's expert testimony on the various flaws in Dr. King's proposed opinions, Pfizer's marketing and promotional efforts with respect to Neurontin, and the off-label prescribing of drugs generally and Neurontin specifically, are directly relevant given Plaintiffs intent to introduce evidence on these issues. • Plaintiff's Rule 403 objections are not well taken. Dr. Grabowski's expert opinions are relevant and pose no risk of unfair prejudice, confusion of the issues, or misleading the jury. • Plaintiff's Rule 608 objections are not well taken. Dr. Grabowski's opinions are properly the subject of expert testimony, and do not constitute improper impeachment evidence under FRE 608. • Plaintiff's Rule 702 and 703 objections are not well taken. The testimony is based upon sufficient facts or data, is the product of reliable principles and methods, and Dr. Grabowski has applied the

	principles and methods reliably to the facts of the case. • Plaintiff's Daubert challenge to Dr. Grabowski's testimony is (i) untimely, and (ii) totally unsupported. • Dr. Grabowski is eminently qualified based on his experience, education and training as an economist to testify in this matter. • Dr. Grabowski's expert opinions do not constitute improper legal opinions. To the extent they criticize the flawed opinions and methodology of Plaintiff's economic expert Dr. King, they are proper expert opinion grounded in Dr. Grabowski's experience and expertise as an economist and will be helpful to the jury. • Dr. Grabowski may properly opine that there is no economic of statistical basis for the opinions that Dr. King seeks to offer in this case. • Dr. Grabowski may properly cite to the opinions of other experts in this case as part of the foundation for his expert opinions.
2:21—3:4 and First Demonstrative	• Plaintiff's non-specific Rule 401, 403, 608 and 702-04 objections are not well taken. Dr. Grabowski's proposed testimony is plainly relevant, not improper opinion on how to weigh evidence or improper legal opinion, fully within the scope of permissible expert testimony, not improper impeachment evidence, and not conclusory or argumentative. • The testimony is based upon sufficient facts or data, is the product of reliable principles and methods, and Dr. Grabowski has applied the principles and methods reliably to the facts of the case.
3:5—7	• Plaintiff's non-specific Rule 401, 403, and 702-04 objections are not well taken. Dr. Grabowski's proposed testimony is plainly relevant, not improper opinion on how to weigh evidence or improper legal opinion, fully within the scope of permissible expert testimony, and not conclusory or argumentative.
3:20—21	• Plaintiff's non-specific Rule 401, 403, 608 and 702-04 objections are not well taken. Dr. Grabowski's proposed testimony is plainly relevant, not improper opinion on how to weigh evidence or improper legal opinion, fully within the scope of permissible expert testimony, not improper impeachment evidence, and not conclusory or argumentative. • The testimony is based upon sufficient facts or data, is the product of reliable principles and methods, and Dr. Grabowski has applied the

	principles and methods reliably to the facts of the case.
3:23—4:1	• Plaintiff's non-specific Rule 401, 403, 608 and 702-04 objections are not well taken. Dr. Grabowski's proposed testimony is plainly relevant, not improper opinion on how to weigh evidence or improper legal opinion, fully within the scope of permissible expert testimony, not improper impeachment evidence, and not argumentative. • The testimony is based upon sufficient facts or data, is the product of reliable principles and methods, and Dr. Grabowski has applied the principles and methods reliably to the facts of the case.
4:2—4	• Plaintiff's objection that "There is no 'Plaintiffs counsel's chart" is unfounded as the subject chart was provided to Dr. King by Plaintiff's counsel. • Plaintiff's non-specific Rule 401, 403, 608 and 702-04 objections are not well taken. Dr. Grabowski's proposed testimony is plainly relevant, not improper opinion on how to weigh evidence or improper legal opinion, fully within the scope of permissible expert testimony, not improper impeachment evidence, and not argumentative. • The testimony is based upon sufficient facts or data, is the product of reliable principles and methods, and Dr. Grabowski has applied the principles and methods reliably to the facts of the case.
4:4—5	• Plaintiff's non-specific Rule 401, 403, 608 and 702-04 objections are not well taken. Dr. Grabowski's proposed testimony is plainly relevant, not improper opinion on how to weigh evidence or improper legal opinion, fully within the scope of permissible expert testimony, not improper impeachment evidence, and not argumentative. • The testimony is based upon sufficient facts or data, is the product of reliable principles and methods, and Dr. Grabowski has applied the principles and methods reliably to the facts of the case.
4:12—15 4:18—19	• Plaintiff's non-specific Rule 401, 403, 608 and 702-04 objections are not well taken. Dr. Grabowski's proposed testimony is plainly relevant, not improper opinion on how to weigh evidence or improper legal opinion, fully within the scope of permissible expert testimony, not improper impeachment evidence, and not conclusory or argumentative. • The testimony is based upon sufficient facts or data, is the product of reliable principles and methods, and Dr. Grabowski has applied the principles and methods reliably to the facts of the case.
Second	• Plaintiff's non-specific Rule 401, 403, 608, 702, and 704 objections are

Demonstrative 4:21—23	not well taken. Dr. Grabowski's proposed testimony is relevant, not improper legal opinion, fully within the scope of permissible expert testimony, not improper impeachment evidence, and not conclusory or argumentative. • The testimony is based upon sufficient facts or data, is the product of reliable principles and methods, and Dr. Grabowski has applied the principles and methods reliably to the facts of the case.
5:6—8	• Plaintiff's non-specific Rule 401, 403, 608, 702, and 704 objections are not well taken. Dr. Grabowski's proposed testimony is relevant, not improper legal opinion, fully within the scope of permissible expert testimony, not improper impeachment evidence, and not conclusory or argumentative. • The testimony is based upon sufficient facts or data, is the product of reliable principles and methods, and Dr. Grabowski has applied the principles and methods reliably to the facts of the case.
5:20—21	• Plaintiff's non-specific Rule 401, 403, 608 and 702-04 objections are not well taken. Dr. Grabowski's proposed testimony is plainly relevant, not improper opinion on how to weigh evidence or improper legal opinion, fully within the scope of permissible expert testimony, not improper impeachment evidence, and not argumentative. • The testimony is based upon sufficient facts or data, is the product of reliable principles and methods, and Dr. Grabowski has applied the principles and methods reliably to the facts of the case.
5:22—23	• Plaintiff's non-specific Rule 702-04 objections are not well taken. Dr. Grabowski's proposed testimony is fully within the scope of permissible expert testimony. • The testimony is based upon sufficient facts or data, is the product of reliable principles and methods, and Dr. Grabowski has applied the principles and methods reliably to the facts of the case.
6:4—7 and Third Demonstrative	• Plaintiff's non-specific Rule 401, 403, 608 and 702-04 objections are not well taken. Dr. Grabowski's proposed testimony is plainly relevant, not improper opinion on how to weigh evidence or improper legal opinion, fully within the scope of permissible expert testimony, not improper impeachment evidence, and not conclusory or argumentative. • The testimony is based upon sufficient facts or data, is the product of reliable principles and methods, and Dr. Grabowski has applied the principles and methods reliably to the facts of the case.

	• Dr. Grabowski may properly cite to the opinions of other experts in this case as part of the foundation for his expert opinions.
7:9—12	• Plaintiff's non-specific Rule 401, 403, 608 and 702-04 objections are not well taken. Dr. Grabowski's proposed testimony is plainly relevant, not improper opinion on how to weigh evidence or improper legal opinion, fully within the scope of permissible expert testimony, not improper impeachment evidence, and neither conclusory nor argumentative. • The testimony is based upon sufficient facts or data, is the product of reliable principles and methods, and Dr. Grabowski has applied the principles and methods reliably to the facts of the case. • Dr. Grabowski may properly cite to the opinions of other experts in this case as part of the foundation for his expert opinions.
7:15—21	• Plaintiff's non-specific Rule 401, 403, 608 and 702-04 objections are not well taken. Dr. Grabowski's proposed testimony is plainly relevant, fully within his expertise as an economist, not improper opinion on how to weigh evidence or improper legal opinion, fully within the scope of permissible expert testimony, and neither conclusory nor argumentative. • The testimony is based upon sufficient facts or data, is the product of reliable principles and methods, and Dr. Grabowski has applied the principles and methods reliably to the facts of the case.
7:22—8.2 8:6	• Plaintiff's non-specific Rule 702-04 objections are not well taken. Dr. Grabowski's proposed testimony is not beyond his expertise and is proper expert testimony under FRE 702-04. • The testimony is based upon sufficient facts or data, is the product of reliable principles and methods, and Dr. Grabowski has applied the principles and methods reliably to the facts of the case. • Dr. Grabowski may properly cite to the opinions of other experts in this case as part of the foundation for his expert opinions.
8:11—12	• Plaintiff's non-specific Rule 401, 403, 608 and 702-04 objections are not well taken. Dr. Grabowski's proposed testimony is plainly relevant, not improper opinion on how to weigh evidence or improper legal opinion, fully within the scope of permissible expert testimony, not improper impeachment evidence, and not argumentative.
9:4	• Plaintiff's Rule 401, 403, 702-04, and 608 objections are not well taken.

Fourth Demonstrative 9:6—14 9:17—20 9:22—10:2 10:4—9	• Dr. Grabowski's proposed testimony on Neurontin off-label prescribing and the flaws in Dr. King's opinions and methodology are relevant given Plaintiff's intent to introduce evidence on these issues. • The testimony is based upon sufficient facts or data, is the product of reliable principles and methods, and Dr. Grabowski has applied the principles and methods reliably to the facts of the case. • Dr. Grabowski's opinions are within his extensive expertise and qualifications as an expert economist and properly within the scope of admissible expert testimony under FRE 702-04. • Dr. Grabowski's opinions do not constitute improper legal opinion or opinion on how to weigh evidence. • Dr. Grabowski's opinions are not improper impeachment evidence. • Dr. Grabowski's opinions are neither conclusory nor argumentative.
10:10—12	• Plaintiff's non-specific Rule 401, 403, 608 and 702-04 objections are not well taken. Dr. Grabowski's proposed testimony is plainly relevant, not improper opinion on how to weigh evidence or improper legal opinion, fully within the scope of permissible expert testimony, not improper impeachment evidence, and not conclusory or argumentative. • The testimony is based upon sufficient facts or data, is the product of reliable principles and methods, and Dr. Grabowski has applied the principles and methods reliably to the facts of the case.
10:15—16 11:3—6	• Plaintiff's non-specific Rule 401, 403, 608 and 702-04 objections are not well taken. Dr. Grabowski's proposed testimony is plainly relevant, not improper opinion on how to weigh evidence or improper legal opinion, fully within the scope of permissible expert testimony, not improper impeachment evidence, and not conclusory or argumentative. • The testimony is based upon sufficient facts or data, is the product of reliable principles and methods, and Dr. Grabowski has applied the principles and methods reliably to the facts of the case.
11:7—11	• Plaintiff's non-specific Rule 401, 403, 608, and 702-04 objections are not well taken. Dr. Grabowski's proposed testimony is plainly relevant, not improper opinion on how to weigh evidence or improper legal opinion, fully within the scope of permissible expert testimony, and not

	argumentative. • The testimony is based upon sufficient facts or data, is the product of reliable principles and methods, and Dr. Grabowski has applied the principles and methods reliably to the facts of the case.
11:16—22 12:2 12:5—9 12:21—23	• Plaintiff's Rule 401, 403, 702-04, and 608 objections are not well taken. • Dr. Grabowski's proposed testimony on Neurontin off-label prescribing and the flaws in Dr. King's opinions and methodology on these issues are plainly relevant to this case given Plaintiff's intent to introduce evidence on these issues. • The testimony is based upon sufficient facts or data, is the product of reliable principles and methods, and Dr. Grabowski has applied the principles and methods reliably to the facts of the case. • Dr. Grabowski's opinions are within his expertise as an expert economist and properly within the scope of admissible expert testimony under FRE 702-04. • Dr. Grabowski's opinions do not constitute improper legal opinion or opinion on how to weigh evidence. • Dr. Grabowski's opinions are not improper impeachment evidence. • Dr. Grabowski's opinions are neither conclusory nor argumentative. • Dr. Grabowski is undoubtedly eminently qualified to offer expert testimony in this case.
13:1—8	• Plaintiff's non-specific Rule 401, 403, 608, and 702-04 objections are not well taken. Dr. Grabowski's proposed testimony is plainly relevant, not improper opinion on how to weigh evidence, fully within the scope of permissible expert testimony, not improper impeachment evidence, and not argumentative. • The testimony is based upon sufficient facts or data, is the product of reliable principles and methods, and Dr. Grabowski has applied the principles and methods reliably to the facts of the case. The factual foundation for Dr. Grabowski's opinions is fully set forth in his report.

	Response to Objections to Dr. Granacher's Expert Witness Statement
Objection	**Response**
8:1-9	• Plaintiff's non-specific Rule 702 objection is not well taken. The testimony is based upon sufficient facts and data, is the product of reliable principles and methods, and Dr. Granacher has applied the principles and methods reliably to the facts of the case. • Plaintiff's timeliness objection based on an MDL scheduling order is not well taken for multiple reasons. First, as a specific causation expert, Dr. Granacher merely addresses general causation issues that necessarily implicate specific causation issues. *See, e.g., Norris v. Baxter Healthcare Corp., 397 F.3d 878, 881* (10th Cir. 2005) ("[W]ithout general causation, there can be no specific causation."). Dr. Maris, Plaintiff's specific causation expert, does precisely the same thing, without the same level of medical training or clinical experience as Dr. Granacher. *See, e.g.,* Maris Direct Statement, at 4 (opining generally that "Neurontin Can Cause Suicides"). Dr. Granacher thus was timely disclosed. Second, if Plaintiff truly believed that Dr. Granacher's disclosure violated an MDL deadline, Plaintiff should have raised the issue with Judge Saris at or soon after the designation in the MDL proceedings, not nearly two years later, on the eve of trial in this case. Dr. Granacher's report – disclosed in 2008 – detailed the issues that Plaintiff is now challenging. *See, e.g.,* November 10, 2008 Report, at 6-11 (discussing general causation matters, and noting that "before an expert can consider whether Neurontin caused a suicide in any particular case, the expert must conclude that Neurontin is capable of causing suicide in the first place"). Dr. Granacher was deposed on these topics, and Plaintiff did not object to the timeliness of the disclosure, or claim any prejudice from the purported late disclosure. Having waited over 18 months, Plaintiff cannot now be heard to complain, on the eve of trial, that the disclosure was late. • Dr. Granacher is an accomplished psychiatrist who is also board-certified in general psychiatry, geriatric psychiatry, and clinical psychopharmacology. He also did residencies in neurology. He has significant experience treating suicidal patients. He is eminently qualified to opine about these matters. Further, Dr. Granacher is much more qualified than Dr. Maris – who is not a medical doctor and instead has a Ph.D in a non-scientific field – and who is attempting to give some opinion testimony about general causation/liability. • The opinions are not inappropriately duplicative because (1) it is testimony from a specific causation expert with a different background (psychiatry) than Defendants' general causation experts; (2) general causation is a necessary precursor to specific causation; and (3) Dr.

	Granacher makes clear that he is relying on the opinions set forth by Dr. Charles Taylor and Dr. Robert Gibbons. *See* November 11, 2008 Report, at 7. • Although "bolstering" another witness is not a proper objection, Dr. Granacher's specific causation opinion is premised on the irrefutable proposition that you cannot have specific causation if you do not have general causation. To the extent hat Plaintiff's specific causation expert, Dr. Maris, speaks to general causation, Dr. Granacher must be permitted to do so as well. • Dr. Granacher's testimony meets the reliability requirement. He has been treating patients with psychiatric issues for over 35 years, and has significant experience treating suicidal patients. Experience, knowledge, and training are clearly appropriate bases for opinion testimony under FRE 702. Dr. Granacher has further discussed at length is familiarity with research on these issues. Plaintiff is free to cross-examine Dr. Granacher on the applicability of his vast experience treating suicidal patients over 35 years to general principles. • The non-specific objections under Rules 702 and 403 to Dr. Granacher's opinion regarding the labeling for Neurontin are not well taken. As a practicing psychiatrist with 35-plus years' worth of experience prescribing medications (including Neurontin), and an expert familiar through training, study, and research about the risks and benefits of Neurontin, Dr. Granacher is well-qualified to testify about the content and adequacy of the label. Defendants can cross-examine Dr. Granacher about whether the potential risks and benefits of the medication were adequately set forth. • Plaintiff's non-specific Rule 403 objection is not well-taken. The evidence is clearly relevant, and has no unfair prejudicial effect.
8:16—19	• Plaintiff's generalized Rule 702 objection is not well taken. The rule of parsimony is a well-accepted rule of science and logic that the most reasonable and simplest explanation should prevail. Plaintiff has offered no authority or evidence undermining that principle.
10:1—2	• Dr. Granacher is an accomplished psychiatrist with over 35 years of clinical experience, and significant experience treating suicidal patients. Included in that experience is 23 years of service as the psychiatrist on call to the St. Joseph Hospital emergency department, where he evaluated all suicidal patients in this 466 bed hospital. He is eminently qualified to opine about the impact of Mr. Smith's pain on his psyche. On foundation, there is ample evidentiary support that Mr. Smith made the statements evidencing his suicidal thoughts. Plaintiff is free to cross-examine Dr. Granacher on the evidence and his opinions.

	• Statements related to Mr. Smith's suicidal ideations are not hearsay because they are not offered for the truth of the matter asserted. Further, they are admissions of a party opponent. Even if the statements are hearsay, they are covered by multiple exceptions, including statements about then existing mental, emotional, or physical condition (FRE 803(3)) statements for medical diagnosis or treatment (FRE 803(4)), and public records and reports (FRE 803(8)). Even if the statements are hearsay not within an exception, they are admissible under FRE 703. In addition, Plaintiff is seeking to have its own expert(s) testify about ideations allegedly uttered after Mr. Smith began taking Neurontin.
13:19—21	• Dr. Granacher is an accomplished psychiatrist who is also board-certified in general psychiatry, geriatric psychiatry, and clinical psychopharmacology (which is the field of medical science that deals with the diagnosis and treatment of mental disorders with medications). He also did residencies in neurology. He has spent his career reviewing and interpreting dosage information set forth on drug labels. He has ample foundation to give this testimony, and Plaintiff is free to cross examine him. • There is no valid objection asserted. Plaintiff is free to cross-examine Dr. Granacher about the accuracy of the testimony.
13:30—35	• Dr. Granacher is an accomplished psychiatrist who is also board-certified in general psychiatry, geriatric psychiatry, and clinical psychopharmacology. He also did residencies in neurology. He is eminently qualified to render this opinion, and the opinion is not an affirmative statement that Lortab caused Mr. Smith to feel "loopy." His opinion is instead simply that a differential diagnosis (something referenced by Plaintiff's specific causation expert, Dr. Granacher) needs to be done. In other words, an examiner needs to rule out other potential causes of a condition before attributing that condition to Neurontin. Dr. Granacher simply notes that Lortab needs to be ruled out as a potential cause, and nothing more. Plaintiff is free to cross-examine Dr. Granacher on the challenged testimony.
15:16—17	• Dr. Granacher's testimony meets the reliability requirements of Rule 702, and has a sufficient foundation. He is board-certified in general psychiatry, geriatric psychiatry, and clinical psychopharmacology (which is the field of medical science that deals with the diagnosis and treatment of mental disorders with medications). He has been treating patients with psychiatric issues for over 35 years, and predictably has significant experience treating patients with depression using anti-depressants. Experience, knowledge, and training are clearly appropriate bases for opinion testimony under FRE 702. Plaintiff is free to cross-examine Dr. Granacher on the accuracy of this statement.

15:17—20	• Dr. Granacher's testimony meets the reliability requirements of Rule 702, and has a sufficient foundation. He is board-certified in general psychiatry, geriatric psychiatry, and clinical psychopharmacology (which is the field of medical science that deals with the diagnosis and treatment of mental disorders with medications). He has been treating patients with psychiatric issues for over 35 years, and predictably has significant experience treating patients with depression using anti-depressants. Experience, knowledge, and training are clearly appropriate bases for opinion testimony under FRE 702. Plaintiff is free to cross-examine Dr. Granacher on the accuracy of this statement.
15:22—23. 16:1-8	• Dr. Granacher's testimony meets the reliability requirements of Rule 702, has a sufficient foundation, and is not speculative. He has been treating patients with psychiatric issues for over 35 years, and predictably has significant experience treating patients with depression, on anti-depressants, and who are suicidal. Experience, knowledge, and training are clearly appropriate bases for opinion testimony under FRE 702. Plaintiff is free to cross-examine Dr. Granacher on his analysis.
20:17—20	• Statements related to Mr. Smith's suicidal ideations are not hearsay because they are not offered for the truth of the matter asserted. Further, they are admissions of a party opponent. Even if the statements are hearsay, they are covered by multiple exceptions, including statements about then existing mental, emotional, or physical condition (FRE 803(3)) statements for medical diagnosis or treatment (FRE 803(4)), and public records and reports (FRE 803(8)). Even if the statements are hearsay not within an exception, they are admissible under FRE 703. In addition, Plaintiff is seeking to have its own expert(s) testify about ideations allegedly uttered after Mr. Smith began taking Neurontin. • Plaintiff's non-specific 403 objection is not well taken. Mr. Smith's pre-Neurontin suicidal ideations are highly relevant, and has no unfair prejudicial effect.
22:2—3	• Dr. Granacher's testimony meets the reliability requirements of Rule 702, has a sufficient foundation, and is not speculative. He is board-certified in general psychiatry, geriatric psychiatry, and clinical psychopharmacology (which is the field of medical science that deals with the diagnosis and treatment of mental disorders with medications). He has been treating patients with psychiatric issues for over 35 years, and predictably has significant experience treating patients with depression using anti-depressants. Experience, knowledge, and training are clearly appropriate bases for opinion testimony under FRE 702. Plaintiff is free to cross-examine Dr. Granacher on the accuracy of this statement.
22:19—23	• Statements related to Mr. Smith's suicidal ideations are not hearsay because they are not offered for the truth of the matter asserted. Further,

	they are admissions of a party opponent. Even if the statements are hearsay, they are covered by multiple exceptions, including statements about then existing mental, emotional, or physical condition (FRE 803(3)) statements for medical diagnosis or treatment (FRE 803(4)), and public records and reports (FRE 803(8)). Even if the statements are hearsay not within an exception, they are admissible under FRE 703. In addition, Plaintiff is seeking to have its own expert(s) testify about ideations allegedly uttered after Mr. Smith began taking Neurontin.
176-2, p.2	• Dr. Granacher is an accomplished psychiatrist with over 35 years of clinical experience, and significant experience treating suicidal patients. Included in that experience is 23 years of service as the psychiatrist on call to the St. Joseph Hospital emergency department, where he evaluated all suicidal patients in this 466 bed hospital. He is eminently qualified to opine about the impact of Mr. Smith's pain on his psyche. There is ample evidentiary support for the statements evidencing Mr. Smith's thoughts. • Statements related to Mr. Smith's suicidal ideations are not hearsay because they are not offered for the truth of the matter asserted. Further, they are admissions of a party opponent. Even if the statements are hearsay, they are covered by multiple exceptions, including statements about then existing mental, emotional, or physical condition (FRE 803(3)) statements for medical diagnosis or treatment (FRE 803(4)), and public records and reports (FRE 803(8)). Even if the statements are hearsay not within an exception, they are admissible under FRE 703. In addition, Plaintiff is seeking to have its own expert(s) testify about ideations allegedly uttered after Mr. Smith began taking Neurontin.
176—2, p.23	• Statements related to Mr. Smith's suicidal ideations are not hearsay because they are not offered for the truth of the matter asserted. Further, they are admissions of a party opponent. Even if the statements are hearsay, they are covered by multiple exceptions, including statements about then existing mental, emotional, or physical condition (FRE 803(3)) statements for medical diagnosis or treatment (FRE 803(4)), and public records and reports (FRE 803(8)). Even if the statements are hearsay not within an exception, they are admissible under FRE 703. In addition, Plaintiff is seeking to have its own expert(s) testify about ideations allegedly uttered after Mr. Smith began taking Neurontin.

	Response to Objections to Dr. Jacob's Expert Witness Statement
Objection	**Response**
6:17	• Plaintiff's non-specific Rule 702 objection is not well taken. The testimony is based upon sufficient facts and data, is the product of reliable principles and methods, and Dr. Jacobs has applied the principles and methods reliably to the facts of the case. • Plaintiff cites no authority for the proposition that the FDA has a "regulatory definition for causation," and Pfizer is aware of none. Plaintiff clearly views opinions using the verb "cause" as appropriate for expert testimony. *See, e.g.,* Maris Direct Statement, at 2 ("Many factors cause a suicide."), 3 ("Prescription Drugs Can Cause Suicides."), 6 ("Neurontin Can Cause Suicides."), 8 ("Neurontin was a Substantial Contributing Factor in or Cause of Richard Smith's suicide."). *See also id.* ("Richard Smith Did Not Kill Himself Because of his Chronic Physical Pain.").
7:19—8:8	• Plaintiff's non-specific Rule 702 objection is not well taken. The testimony is based upon sufficient facts and data, is the product of reliable principles and methods, and Dr. Jacobs has applied the principles and methods reliably to the facts of the case. • The opinion is not beyond the scope of Dr. Jacobs's reports. His November 10, 2008 report states, *inter alia*, that the FDA found that "for Neurontin there were no suicides, no suicide attempts and the relative risk was 1.57 with a confidence interval that demonstrated that the relative risk was not statistically significant." Report at 7. • The opinion is not inappropriately duplicative of Dr. Gibbons's opinion because (1) it is testimony from a specific causation expert with a different background than Dr. Gibbons; (2) general causation is a necessary precursor to specific causation (see below); and (3) Dr. Jacobs states that he relies on Dr. Gibbons's analysis, and such reliance is appropriate. • Although "bolstering" another witness is not a proper objection, Dr. Jacobs's specific causation opinion is premised on the irrefutable proposition that you cannot have specific causation if you do not have general causation. Plaintiff's specific causation expert, Dr. Maris, discusses the FDA meta-analysis. • On 403, the evidence is clearly relevant, particularly given Plaintiff's intent to introduce evidence on these issues. If Plaintiff is going to be permitted to discuss the FDA's meta-analysis, Pfizer must be permitted to respond.
8:9—9:15	• Plaintiff's non-specific Rule 702 objection is not well taken. The testimony

	is based upon sufficient facts and data, is the product of reliable principles and methods, and Dr. Jacobs has applied the principles and methods reliably to the facts of the case. • The opinion is not beyond the scope of Dr. Jacobs's reports. His December 20, 2007 report covered the FDA analysis in detail, discussing, *inter alia,* the trials involving 5,194 patients, the results of "no completed suicide or attempted suicide," and the .039% versus .037% suicidal ideation rates. His November 10, 2008 report discussed, *inter alia*, "three well-controlled randomized trials studying Neurontin in patients with psychiatric disorders – panic disorder, bipolar disorder, and social phobia" and how, "[u]sing Hamilton Depression (or HAM-D) and Hamilton Anxiety (HAM-A) scales, these studies showed no significant differences from baseline reports of depression or anxiety at any time during the study period. These results indicate that, in these psychiatric populations, there was no worsening of depression or anxiety." Report, at 12. • The opinion is not inappropriately duplicative of Dr. Gibbons's opinion because (1) it is testimony from a specific causation expert with a different background than Dr. Gibbons; (2) general causation is a necessary precursor to specific causation (see below); and (3) Dr. Maris states that he relies on Dr. Gibbons's analysis, and such reliance is appropriate.. • Although "bolstering" another witness is not a proper objection, Dr. Jacobs's specific causation opinion is premised on the irrefutable proposition that you cannot have specific causation if you do not have general causation. Plaintiff's specific causation expert, Dr. Maris, discusses the FDA meta-analysis. • On 403, the evidence is clearly relevant, particularly given Plaintiff's intent to introduce evidence on these issues. If Plaintiff is going to be permitted to discuss the FDA's meta-analysis, Pfizer must be permitted to respond. • Dr. Jacobs was clear in his reliance on Dr. Gibbons's report, stating in his November 10, 2008 report, at 7, that, in regards to the FDA Alert, "I am relying upon the expert reports of Dr. Gibbons."
25:9—14	• Plaintiff's non-specific Rule 702 objection is not well taken. The testimony is based upon sufficient facts and data, is the product of reliable principles and methods, and Dr. Jacobs has applied the principles and methods reliably to the facts of the case. • The opinion is not beyond the scope of Dr. Jacobs's reports. His November 10, 2008 report discusses, *inter alia,* the FDA's data regarding suicidal behavior and ideation (as opposed to actual suicide). *See* Report, at 7. His November 10, 2008 report states, *inter alia*, that the FDA found that "for Neurontin there were no suicides, no suicide attempts and the relative risk

	was 1.57 with a confidence interval that demonstrated that the relative risk was not statistically significant." Report at 7. • On 403, the evidence is clearly relevant, particularly given Plaintiff's intent to introduce evidence on these issues. If Plaintiff is going to be permitted to discuss the FDA's meta-analysis, Pfizer must be permitted to respond.
29:8—23	• The referenced agreement regarding drafts of expert reports did not cover what efforts experts undertook to collect information, review documents, and investigate facts. More specifically, the agreement was as follows: "it is hereby stipulated and agreed upon by counsel [for the parties] that drafts of expert reports are not discoverable. It is further stipulated and agreed upon that drafts of expert reports is a subject about which the parties shall not inquire at depositions of the parties' experts." November 7, 2007 letter from Plaintiff's counsel. Dr. Maris's psychological autopsy form – which seeks biographical, health, familial, and other information about Mr. Smith – was nothing close to a draft report in this case. Dr. Maris testified at deposition that the report is a separate form he has used in other cases to collect information relevant to his analysis. Dr. Maris was questioned at length during his deposition about the preparation of the psychological autopsy form in connection with his efforts to collect information, review documents, and investigate facts. A generic form of the report was marked as Exhibit 29 to Dr. Maris's deposition, and the form used in the Smith case was marked as Exhibit 30 to Dr. Maris's deposition. Plaintiff's counsel never objected based upon the agreement covering draft reports to a single question in what amounts to several pages of testimony elicited regarding the psychological autopsy. *See* Maris Deposition Tr., at 399:7 to 412:10 (discussing psychological autopsy form generally); 428:7 to 450:4 (discussing psychological autopsy form in the Smith case, how information was collected for the form, and Dr. Maris's review of the form). The information regarding what information Dr. Maris collected in this case, and how he collected it, is clearly relevant and admissible.
177-2, p.1	• The June 2006 Pfizer submission to the FDA that is the subject of this demonstrative shows the results of Pfizer's placebo-controlled trials for completed suicide, suicide attempt, and suicidal ideation. It was previously disclosed by Dr. Jacobs. In fact, Dr. Jacobs's December 20, 2007 Report discussed the submission in detail, describing the contents of "Pfizer's June 2006 submission to the FDA," which showed, *inter alia*, that "[t]here were no cases of completed suicide or attempted suicide in any of the placebo-controlled studies," and that "0.039% of Gabapentin patients and 0.037% of placebo patients reported suicidal ideation." Report, at 11.

RESPONSE TO OBJECTIONS TO SHEILA WEISS SMITH, PH.D.'S EXPERT WITNESS STATEMENT

Plaintiff's Objection	Defendants' Response
Slide 18	There is no "Slide 18" in the demonstratives used by Dr. Weiss-Smith
4:18	Plaintiff claims that Dr. Weiss-Smith has not previously disclosed her opinion of the quality of the data in the FDA AERS database. However, at page 14 in her report dated December 20, 2007, Dr. Weiss-Smith wrote, "As detailed below, these direct-to-FDA reports produced a significant reporting bias in the AERS database, such that one would not reach any reliable conclusion regarding a signal." In addition, in her supplemental report, dated November 7, 2008, Dr. Weiss-Smith goes into great detail regarding the limitation of the AERS database (See, e.g., p. 27-31).
8:14	Plaintiff claims that it is beyond the scope of Dr. Weiss-Smith's expertise to opine on the effect of publicity on reporting of suicidal events. Dr. Weiss-Smith is a pharmacoepidemiologist, who has published extensively on methodology to determine the source of various biases in adverse event reports. In her direct testimony, as well as in her expert reports, Dr. Weiss-Smith provides the bases for her opinion that attorney publicity played a major role in the reporting of suicidal behavior events for Neurontin. Plaintiff fails to provide any evidence that the prejudice of Dr. Weiss-Smith opinion outweighs the probative value or that such an opinion is irrelevant. Dr. Weiss will testify that the ONLY increase in reporting of suicide events occurred when plaintiff's attorney's sent in 258 adverse event reports to FDA over a 2-3 day period in 2005 – at no other time (either before or after June 2003) was there an increased rate of reporting of suicide events for Neurontin.
9:5	Plaintiff misstates the ruling of MDL court regarding plaintiff's expert, Dr. Blume. The MDL court has never held that Dr. Blume is qualified to provide a clinical or medical opinion. The statement made by Dr. Weiss-Smith here is merely restating that fact. There is no prejudice to plaintiff by Dr. Weiss-Smith by stating that Dr. Blume is not qualified to provide a clinical evaluation of adverse events.
10:9	The opinion is not inappropriately duplicative because it is testimony from a general causation expert with a different background than Pfizer's other experts. Pfizer restates and incorporates by reference its response to Plaintiff's objection to 9:5
13:2	Pfizer restates and incorporates by reference its response to Plaintiff's objection to 8:14
13:6	Pfizer restates and incorporates by reference its response to Plaintiff's objection to 8:14
15:1	Plaintiff claims that Dr. Weiss-Smith is not qualified to determine whether completed suicide or suicide attempt are "serious." However, for the purposes of Dr. Weiss-Smith's analysis of the AERS database, such a determination does not require any form of clinical assessment of individual cases. The determination of the seriousness of the completed suicide or suicide attempt is made by the reporter and/or the company when filling out the MedWatch report form – it is merely a box that is checked. Thus, Dr. Weiss-Smith does not have to review the individual case reports to determine whether the case was serious. The statement by plaintiff that Dr. Weiss-Smith "ignores suicide

	attempt reports that are coded by reporters as non-serious" makes little sense. Under FDA regulations, any event that is "life-threatening" is considered "serious." A suicide attempt is by definition life-threatening.
15:12	Plaintiff claims that Dr. Weiss-Smith used faulty methodology when she created the plot of Proportional Reporting Rates for completed suicide and suicide attempt for Neurontin. In her report dated November 7, 2008, Dr. Weiss-Smith wrote: > I understand that I was criticized by Mr. Altman, in his declaration for graphing values of zero. (Altman K. Declaration 2008, para 37). Zero is the software's default for no value. (Qscan User Manual Version 3.2) PRR cannot be calculated for terms that are not reported. The baseline value for a PRR – which signifies no difference in reporting rates – is 1.0. A PRR above 1.0 means that particular term is more common (proportionally) among reports for the drug under study than among the background (typically all other) drugs. There is no consensus in the pharmacovigilance community on what PRR value is considered to be in excess of expected (statistically significant), though a value of 2.0 or above, often with additional requirements such as a chi-squared above 4 and at least 3 drug-event pairs, is frequently cited in the literature. I graphed the PRR's, not cumulative percentages, as erroneously noted by Mr. Altman. The start date was selected because that was the year gabapentin was first approved and the reporting of the first suicide attempt reports. The jump in my graph from zero to 1.0 does not mean that there was an increase in the PRR, but that the PRR could now be calculated for that preferred term. Dr. Weiss-Smith has clearly provided an explanation for her analysis and methodology. The point made by Plaintiff is a point of cross-examination, not a basis to limit Dr. Weiss-Smith's expert testimony. .
16:1	Pfizer restates and incorporates by reference its response to Plaintiff's objection to 8:14. Regarding the letter from FDA dated April 12, 2005, Plaintiff asserts that Dr. Weiss-Smith mischaracterizes the letter. Dr. Katz wrote, "Further, in the absence of an appropriate control group, it will be difficult, if not impossible, to assess the role of any other factors that might explain these events, such as concomitant medications." This clearly explains the difficulty, if not impossibility, of using uncontrolled data (including adverse event reports) to evaluate the risk of suicidal behavior with Neurontin treatment.
17:1	Plaintiff claims that Dr. Weiss-Smith lacks any basis for her opinion that the reporting of suicide-related events for all drugs are affected by the reporting of similar events for

	other drugs. However, plaintiff mischaracterizes Dr. Weiss-Smith's opinion. In her report dated November 7, 2008, Dr. Weiss-Smith wrote: > Mr. Altman declares that there was no notoriety bias in reporting of suicides based solely on the timing of his involvement and the involvement of his law firm. (Altman Declaration 2008, para 30) This ignores the fact that there are many other people and entities reporting events to the FDA. Indeed, the evidence suggests that there was significant "notoriety bias" surrounding the reporting of suicide-related adverse events during the period in question. As shown in Figure 3, the number of suicides (completed suicides) reported to the FDA regardless of drug more than doubled from 1027 in 2002 to 2119 reports in 2003, while suicide reports mentioning gabapentin increased 2.3-fold from 40 in 2002 to 92 in 2003. The reporting of completed suicides (all drugs) appears to have peaked in 2005 at 2899 reports. Also during this same time period both the FDA and European regulators issued warnings about a possible link between SSRI antidepressants and suicidal behaviors in children and adolescents in 2003 and FDA held an advisory committee meeting on this subject in early (February 3rd) 2004. Such events are known to stimulate reporting. (FDA Drug Safety Newsletter 2008) Mr. Altman's "analysis" does not account for this increase in the reporting of suicides in the AERS database. Dr. Weiss-Smith goes on to cite Bridges et al. (2008), and she wrote: > In this paper, the authors evaluated data on deaths for which suicide was listed as the underlying cause of death among 10-19 year olds in the National Vital Statistics Systems. They found that although the overall rate of suicide decreased by 5.3% between 2004 and 2005, the rate of suicide during these years was significantly greater than expected based on the 1999-2003 trend. Thus, there was a significant increase in suicide rates between 2003 and 2004, at the same time as the increase in overall reports of suicide in AERS (for all drugs). This trend in increased reporting of suicide events, for all drugs, is clearly relevant to the issue of whether an increase in reporting of suicide events by patients on Neurontin is a true association or if it is merely the result of an overall increase in reporting of suicide events for all drugs. Plaintiff fails to show any prejudice as a result of this analysis.
Slides 10, 11, 12, 14, 15	Pfizer agrees that notoriety bias starts around June of 2003. The plots will be edited accordingly.

Slide 12	Pfizer restates and incorporates by reference its response to Plaintiff's objection to 15:12

RESPONSE TO OBJECTIONS TO JANET ARROWSMITH, M.D.'S EXPERT WITNESS STATEMENT

Plaintiff's Objection	Defendants' Response
3:13	The opinion is not inappropriately duplicative because it is testimony from a general causation expert with a different background than Pfizer's other experts.
3:18	The opinion is not inappropriately duplicative because it is testimony from a general causation expert with a different background than Pfizer's other experts.
9:19	Plaintiff objects that there is a lack of foundation because of the lack of production of certain documents during the "Parke-Davis era." However, Dr. Arrowsmith here is relying on documents that were submitted to FDA, including but not limited to periodic reports, which Plaintiff concedes were indeed produced in this litigation. The "safety activities" of the company are reflected in these documents. The opinion is not inappropriately duplicative because it is testimony from a general causation expert with a different background than Pfizer's other experts.
10:5	Plaintiff objects on the basis of speculation, but Dr. Arrowsmith here relies on published peer-reviewed literature for her opinion that the patient populations at issue here have an increased risk of suicide regardless of the treatment received. Contrary to plaintiff's assertions in this objection, the number of patients in the Neurontin clinical trials is irrelevant to the issue of the established suicide rate in the various patient populations. The foundation is laid in the preceding sentences of her testimony.
12:10	Plaintiff objects that FDA regulations do not allow uncontrolled trials to establish benefits. Dr. Arrowsmith, however, is not opining that uncontrolled trials are to be used by FDA to satisfy the regulatory requirement that a medicine have benefits. Rather, her opinion is broader than that, saying that uncontrolled trials "may" help clinicians to determine "potential benefits" of a new medicine. There is a distinction between a regulatory requirement and a clinical observation, which plaintiff is choosing to ignore here.
14:9	Dr. Blume stated in her deposition that the difference between the rate of depression in Neurontin-treated (1.8%) and placebo-treated patients (1.1%) was not statistically significant. (See deposition of Dr. Cheryl Blume, 11/13/07 527:19-528:4; 528:22-25). Pfizer will edit Dr. Arrowsmith's testimony accordingly.
14:13	Plaintiff objects that Dr. Arrowsmith is speculating that had the FDA reviewers concluded that Neurontin increased the risk of depression or suicide, it would have required a warning in the label. However, because FDA is charged with overseeing public safety when it comes to medicines, if FDA determined that there was an increased risk for suicide or depression, it would be obligated to include a warning in the medicine's labeling. The absence of a warning does indeed mean that FDA has determined that one is not necessary.
15:3	Plaintiff cites only one of several documents that Dr. Arrowsmith used to form her

	opinion that Dr. McCormick of FDA did not conclude that the clinical trial data demonstrated an increased risk for depression or suicidal behavior. Plaintiff only cites the earliest of the documents (Ex. 7563), but excludes the First Safety Update (Ex. 7068) and Fourth Safety Update (Ex. 7562). The point made by Plaintiff is a point of cross-examination, not a basis to limit Dr. Arrowsmith's expert testimony.
15:16	Pfizer restates and incorporates by reference its response to Plaintiff's objection to 15:3
16:5	Dr. Arrowsmith is opining that Dr. McCormick of FDA reviewed the available data before concluding that Neurontin was safe and effective and should be approved for marketing when used in accordance with the approved labeling. Plaintiff's citation of the statement by Dr. McCormick is irrelevant to the issue of the overall conclusion by FDA that Neurontin is safe and effective. The point made by Plaintiff is a point of cross-examination, not a basis to limit Dr. Arrowsmith's expert testimony.
21:11	The opinion is not inappropriately duplicative because it is testimony from a general causation expert with a different background than Pfizer's other experts.
22:17	Plaintiff asserts that the April 12, 2005 letter from Dr. Russel Katz of FDA does not state that uncontrolled data are not useful in evaluating whether Neurontin was associated with increased risk. However, Dr. Katz wrote, "Further, in the absence of an appropriate control group, it will be difficult, if not impossible, to assess the role of any other factors that might explain these events, such as concomitant medications." This clearly explains the difficulty, if not impossibility, of using uncontrolled data to evaluate the risk of suicidal behavior with Neurontin treatment. The opinion is not inappropriately duplicative because it is testimony from a general causation expert with a different background than Pfizer's other experts.
23:6	See response to objection 22:17 regarding statement on uncontrolled data. Dr. Arrowsmith is allowed to provide opinion testimony, including her opinions and bases for her criticisms of plaintiff's expert, Dr. Blume. The point made by Plaintiff is a point of cross-examination, not a basis to limit Dr. Arrowsmith's expert testimony.
23:10	The email from the FDA labeled as DX7392 has been authenticated through Rule 901(b)(1) because Dr. Ruggieri, who is a witness with first-hand knowledge, has attested that the document "is what it is claimed to be." Defendants have submitted an affidavit of Dr. Ruggieri that the DX7392 is a true and accurate copy of the email he received, and he will also be available to testify to that fact. Plaintiff's attempt to impugn his veracity on this matter, which is based on pure speculation, goes to the weight and not admissibility of the evidence. Further, the hearsay rule does not bar admission for three reasons. First, to the extent these exhibits are used to show the internal decision-making process of the FDA, they are not offered to establish the truth of the matter asserted and therefore are not hearsay. Second, these emails fall under the hearsay exception for public records at Rule 803(8) as statements of a public agency. Third, they are admissible under Rule 703 to assist the jury in evaluating Dr. Ruggieri's opinion because they constitute information "of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject" and their "probative value in assisting the jury to evaluate [his] opinion substantially outweighs their prejudicial effect."
23:22	No objection cited by Plaintiff here.

24:7	The opinion is not inappropriately duplicative because it is testimony from a general causation expert with a different background than Pfizer's other experts.
24:21	Dr. Arrowsmith is not speculating as to what FDA detected. Rather she is stating that FDA, despite numerous evaluations of safety data, never stated that it found a signal for increased depression or suicidality based on the Neurontin data. As discussed in response to objection 14:3, FDA would have been obligated to at least discuss the finding of a safety signal.
25:3	The opinion is not inappropriately duplicative because it is testimony from a general causation expert with a different background than Pfizer's other experts.
26:8	Plaintiff is claiming that Dr. Arrowsmith has concluded that there is no "causal link" between Neurontin and suicide. However, Dr. Arrowsmith does not use the word "link" anywhere in her direct testimony. Rather, Dr. Arrowsmith uses the same term used by FDA in the December 16, 2008 Alert – "causal relationship." In addition, despite the assertion that Dr. Arrowsmith used "faulty methodology," Dr. Arrowsmith did not "ignore" the fact that FDA found that antiepileptic drugs had almost twice the risk of suicidal behavior compared to placebo. Indeed, this statement from the Alert refers to the antiepileptic drugs as a class and does not specifically refer only to Neurontin. The point made by Plaintiff is a point of cross-examination, not a basis to limit Dr. Arrowsmith's expert testimony. The opinion is not inappropriately duplicative because it is testimony from a general causation expert with a different background than Pfizer's other experts.
27:21	Dr. Arrowsmith is not speculating. Rather, she provides her opinion and bases for that opinion that FDA would not have removed the language regarding mechanism of action from the Neurontin labeling. Dr. Arrowsmith is a board certified physician and she is qualified to provide an opinion that contradicts that of plaintiff's expert Dr. Blume. The point made by Plaintiff is a point of cross-examination, not a basis to limit Dr. Arrowsmith's expert testimony.
30:13	The opinion is not inappropriately duplicative because it is testimony from a general causation expert with a different background than Pfizer's other experts.
31:6	Plaintiff misstates the ruling by the MDL court. The MDL has not ruled that Dr. Blume has the expertise to provide a clinical assessment of an adverse event report. In contrast to Dr. Arrowsmith, Dr. Blume is not a clinician, so she cannot provide any type of clinical or medical review of an adverse event.
31:9	The "fourth quarter of 2002" is a typo. Pfizer agrees that notoriety bias starts around June of 2003.
32:8	This opinion by Dr. Arrowsmith was disclosed in her supplemental report, dated November 7, 2008. There she wrote: "Third, the various tables setting forth clinical trial withdrawals are incomplete and, when appropriately configured, do not demonstrate any consistent pattern that would raise issues for suicidality."
32:16	Plaintiff claims that Dr. Arrowsmith lacks expertise regarding marketing issues and DDMAC. However, through her experience at FDA, Dr. Arrowsmith has expertise in the federal regulations governing promotion and marketing of prescription medicines. The fact that Dr. Arrowsmith has not responded to a DDMAC letter or worked on specific projects with DDMAC is irrelevant. Dr. Arrowsmith has "scientific, technical

	or other specialized knowledge" regarding DDMAC that "will assist the trier of fact to understand the evidence or to determine a fact in issue." FRE 702.
32:21 – 35:3	Pfizer restates and incorporates by reference its response to Plaintiff's objection to 32:16
Slide 18	The email from the FDA labeled as DX7392 has been authenticated through Rule 901(b)(1) because Dr. Ruggieri, who is a witness with first-hand knowledge, has attested that the document "is what it is claimed to be." Defendants have submitted an affidavit of Dr. Ruggieri that the DX7392 is a true and accurate copy of the email he received, and he will also be available to testify to that fact. Plaintiff's attempt to impugn his veracity on this matter, which is based on pure speculation, goes to the weight and not admissibility of the evidence. Further, the hearsay rule does not bar admission for three reasons. First, to the extent these exhibits are used to show the internal decision-making process of the FDA, they are not offered to establish the truth of the matter asserted and therefore are not hearsay. Second, these emails fall under the hearsay exception for public records at Rule 803(8) as statements of a public agency. Third, they are admissible under Rule 703 to assist the jury in evaluating Dr. Ruggieri's opinion because they constitute information "of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject" and their "probative value in assisting the jury to evaluate [his] opinion substantially outweighs their prejudicial effect."

RESPONSE TO OBJECTIONS TO CHARLES TAYLOR, PH.D.'S EXPERT WITNESS STATEMENT

OBJECTION	**RESPONSE**
12:3; 19:15	Plaintiff objects to portions of Dr. Taylor's proposed testimony pertaining to two studies of the effect of Neurontin on neurotransmitter release. The first study, Dooley, et al., *Stimulus-Dependent Modulation of [3H]Norepinephrine Release from Rat Neocortical Slices by Gabapentin and Pregabalin*, J. of Pharmacology & Experimental Therapeutics (2000) examined Neurontin's effect on neurotransmitter release in rat brain tissue stimulated by potassium. The second study, Brawek & Dooley, et al., *Differential modulation of K+-evoked 3H-neurotransmitter release from human neocortex by gabapentin and Pregabalin*, Naunyn-Schmiedeberg's Arch Pharmacol (2008) examined neurotransmitter release in human brain tissue samples, again after stimulation by potassium. The first portion of testimony that Plaintiff asserts is objectionable contains a detailed explanation of the results of the two studies. The second merely reiterates those findings in brief. Plaintiff's objections are wholly lacking in merit. The very rule of evidence they cite in objecting to Dr. Taylor's proposed testimony, Rule 702, allows expert opinion testimony that is based on sufficient facts or data, and that is the product of reliable principles and methods

that have applied to the facts of the case. Dr. Taylor's opinions regarding the Dooley and Brawek articles clearly satisfy that standard. Indeed, they are based on a basic reading of the text of the two articles and an analysis of the methodologies and results the articles contain. To the extent Plaintiff disagrees with Dr. Taylor's opinions, they should pursue their differences on cross-examination.

Dr. Taylor is a neuroscientist with nearly 30 years in the field, and 25 as a researcher for Pfizer and its predecessors. Much of his career was spent personally researching Neurontin and related chemical compounds. To suggest, as Plaintiff does, that interpreting scientific articles that examine Neurontin's biologic effects is beyond the scope of his expertise is frankly absurd. Equally without merit is Plaintiff's suggestion that the probative value of Dr. Taylor's opinions is outweighed by prejudice. First, Plaintiff misstates the standard; for evidence to be excluded under Rule 403, or for the basis of an expert's opinions to be excluded under Rule 703, their probative value must be "substantially outweighed" by their prejudicial effect. Plaintiff makes no substantive argument as to why that is the case here, nor can they. It is beyond comprehension how the interpretation of relevant scientific literature on the biological effect of a medicine by a neuroscientist with three decades of experience could possibly be considered unduly prejudicial.

RESPONSE TO OBJECTIONS TO DR. ALEX RUGGIERI'S EXPERT WITNESS STATEMENT

OBJECTION	**RESPONSE**
BLANKET OBJECTION	Plaintiff sets forth a lengthy blanket objection to Dr. Ruggieri's proposed testimony, characterizing it as a "recitation of the history of the safety of Neurontin." Plaintiff cites *In re Prempro Prods. Liab. Litig.,* 554 F. Supp. 2d 871, 887 (E.D. Ark. 2008) for the proposition that "[h]aving an expert witness simply summarize a document (which is just as easily summarized by a jury) with a tilt favoring a litigant, without more, does not amount to expert testimony." Plaintiff asserts that Dr. Ruggieri's statement from pages 8 – 14, 14 – 19, and 19 – 22 does not constitute expert opinion testimony under Rule 702. Rule 702 requires that expert opinion testimony be based on "sufficient facts or data" and the application of reliable principles and methods to those facts. Expert opinions that are mere recitations of facts and data, without interpretation may indeed be objectionable. *See In re Trasylol Products Liab. Litig.*, 2010 WL 1737107; Case No. 08-MD-01928 (S.D. Fla. Apr. 27, 2010) (excluding regulatory expert

who did not provide regulatory analysis to support her opinions, but rather relied on her own interpretation of internal corporate documents). The converse, however, is that where an expert endeavors to analyze and interpret the relevant regulatory framework, and apply the facts of the case to that framework, his testimony is not objectionable. Indeed, this Court has already ruled that it is proper for an expert witness to analyze and discuss internal company documents on which he relies for his opinion. Memorandum of the Court, Docket 191. (citing *In re Seroquel Prods. Liab. Litig.*, No. 6:06-MD-1769, 2009 WL 3806436, at *4 (M.D. Fla. July 20, 2009) (holding that expert witnesses may "rely on and discuss [the defendant's] internal corporate documents.")).

In this case, Dr. Ruggieri has indeed examined the history of Neurontin and the pharmacovigilance efforts of Parke-Davis and Pfizer. His opinion that the postmarketing data through 2002 and after showed no safety signal or alert for suicidality or depression, offered as an expert in drug safety and pharmacovigilance, must necessarily be based on the efforts of Parke-Davis and Pfizer to collect, analyze and make use of data about Neurontin, including adverse event reports. His proposed statement clearly states that it is based on the an analysis of regulatory elements including the March 2005 FDA Guidance on Good Pharmacovigilance Practices (page 6), the FDA's mandatory MEDWATCH forms and reporting procedures (Page 8), the FDA's COSTART adverse event dictionary and a later modified version of the COSTART dictionary (page 9), the FDA's MedDRA adverse event reporting dictionary, and the companies' implementation of those procedures. He also reviewed various adverse event reports provided to the FDA by Parke-Davis and Pfizer, including Parke-Davis' Periodic Safety Update Reports and Periodic Reports from 1994 onward, and renders an opinion as to whether they satisfy the FDA's requirements and whether they show evidence of a safety signal (page 11, 14). Finally, Dr. Ruggieri offers his opinion as a clinician and drug safety expert regarding the adequacy of the warnings in Neurontin's labeling (page 23).

To say that Dr. Ruggieri's testimony is merely a summary of Neurontin's history is incorrect. Dr. Ruggieri does indeed summarize the relevant facts on which his opinions are based, but he proceeds to apply those facts to the relevant regulatory background. Given the complex nature of FDA regulations, sufficient background information is absolutely required here in order to assist the jury in determining a fact in issue.

8:5 Plaintiff objects to Dr. Ruggieri's statement that he is familiar with Parke-Davis's and Pfizer's pharmacovigilance activities regarding Neurontin, and whether those efforts satisfied global regulatory

requirements. Specifically, Plaintiff asserts that Defendants failed to produce "documents from the safety surveillance activities during the Parke-Davis era."

Plaintiff's assertion is patently false. Dr. Ruggieri clearly states in his proposed testimony that his opinions are based on Parke-Davis's Periodic Safety Update Reports ("PSURs"), Periodic Adverse Event Drug Reports, clinical data, the 1993 NDA, and other data from the "Parke-Davis era." Moreover, in his February 14, 2009 deposition at pages 340 to 346, the documents on which Dr. Ruggieri's opinions were based were clarified, and Plaintiff's counsel was provided with an opportunity to examine him on that subject.

Plaintiff's objections to Dr. Ruggieri's opinion that global regulatory requirements were satisfied during the Parke-Davis era go to the weight of his opinions rather than their admissibility. They are clearly based on data and facts of the sort reasonably considered by an expert under Rule 702, and should be taken up on cross-examination.

10:12

Plaintiff objects to Dr. Ruggieri's discussion of various COSTART and MedDRA terms for "suicidal" and "suicide attempt" on the basis that they are not found in Exhibits 7399 and 7400, which are the 1985 and 1995 versions of the COSTART dictionaries, respectively. However, Dr. Ruggieri's discussion of those terms refers not to Exhibits 7399 and 7400, but to exhibit 7081, which is the modified version of the COSTART dictionary employed by Parke-Davis during the relevant time period. The terms "suicidal" and "suicide attempt" as objected to by Plaintiff appear on page 46 of the exhibit.

15:10

Plaintiff objects to Dr. Ruggieri's comment that his purported counterpart, Dr. Blume, "concedes that at least by June 2003, the publicity was such that adverse event databases were biased by notoriety or publicity," and his opinion that Neurontin's adverse event database was influenced by litigation, solicitation of reports, and the surrounding publicity.

Plaintiff purports to base their objections on Fed. R. Evid. 403, 702-704, that it is "cumulative" of testimony of Dr. Weiss-Smith, and that it lacks foundation because Dr. Ruggieri does not limit his testimony to the post-June 2003 time period. In fact, Dr. Ruggieri's assertion that Dr. Blume concedes that publicity and notoriety-induced adverse events were on the rise as early as June of 2003 is based on, among other things, paragraph 24 of the April 23, 2008 Declaration of Keith Altman. Therein Mr. Altman states that he was directed by Dr. Blume to eliminate adverse events from his data compilation because of the potential confounding factor of notoriety bias. He stated "Dr. Blume

has always requested that I confine analyses [of adverse event reports] to data before the 3rd quarter of 2003 for signal detection purposes," and that "She clearly recognized that such bias was possible after that point in time and wanted to be sure that her opinions were not influenced by that data."

On pages 185-186 of her November 12, 2007 deposition, Dr. Blume testified that at the very least, notoriety bias was visible in December 2003. Thus, at the very least Dr. Blume has acknowledged that there is evidence to support notoriety bias as early as December 2003, and Keith Altman, who performed data analysis on her behalf before joining the bar as an attorney with the Finkelstein law firm, acknowledged that there is evidence to support notoriety bias in June of that year. The Court should therefore allow Dr. Ruggieri to testify as currently proposed in his statement. Alternatively, Defendants propose amending Dr. Ruggieri's statement to read as follows: "Dr. Blume concedes that at least by December of 2003, the publicity was such that the adverse event databases were biased by notoriety or publicity."

Dr. Ruggieri's reliance on the Altman Declaration and the testimony of Dr. Blume is well-known to Plaintiff. Contrary to their assertion that his opinions were not properly disclosed pursuant to Fed. R. Civ. P. 26(a)(2)(B), Dr. Ruggieri listed both Dr. Blume's deposition transcripts, as well as the Altman Declaration in his Materials Relied On disclosures.

Finally, Plaintiff provides no basis for their Rule 403 objections that the risk of prejudice from Dr. Ruggieri's testimony outweighs its probative value. Not only does Plaintiff ignore the requirement that exclusion under Rule 403 requires probative value to be "substantially outweighed" by risk of prejudice, they offer no explanation as to how the standard is fulfilled here. The Court should not exclude evidence on the basis of unexplained argument. Nor should it exclude his testimony because it is "cumulative" of Dr. Weiss-Smith's testimony without some explanation that it is unduly prejudicial. In any event, the testimony of Dr. Weiss-Smith and Dr. Ruggieri cannot be said to be cumulative. Although they both utilize the same data, they approach it with entirely different skill sets and analyses. Dr. Weiss-Smith's specialty is as a quantitative pharmacoepidemiologist; her testimony is based on a quantitative database analysis of the relevant adverse event reports. In contrast, Dr. Ruggieri's testimony is based on his specialty as an expert in general pharmacovigilance and company practices.

20:17 Plaintiff objects to Dr. Ruggieri's discussion of, and opinions about, Slide 12 in his testimony on the basis of authenticity, hearsay, and its

supposedly unduly prejudicial nature.

Slide 12, or Exhibit 7392, is an e-mail from Dr. Donald Dobbs of the FDA responding to an inquiry by Dr. Ruggieri. It has been authenticated through Rule 901(b)(1), which allows for authentication of a document by a witness with first hand knowledge that a document is what it is claimed to be. Dr. Ruggieri, who is a witness with first-hand knowledge regarding the e-mail, has attested that the document "is what it is claimed to be." Defendants have submitted an affidavit of Dr. Ruggieri that Exhibit 7392 is a true and accurate copy of the email he received, and he will also be available to testify to that fact. Plaintiff's attempt to impugn his veracity on this matter, which is based on pure speculation, goes to the weight and not admissibility of the evidence.

Further, the hearsay rule does not bar admission for three reasons. First, these emails fall under the hearsay exception for public records at Rule 803(8) as statements of a public agency. Second, they are admissible under Rule 703 to assist the jury in evaluating Dr. Ruggieri's opinion because they constitute information "of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject" and their "probative value in assisting the jury to evaluate [his] opinion substantially outweighs their prejudicial effect." Third, and to the extent the Court determines that one of the aforementioned exceptions to the hearsay rule does not apply, the e-mail is being used to show the internal decision-making process of the FDA, rather than to establish the truth of the matter asserted, and therefore does not constitute hearsay.

Finally, as with Plaintiff's other Rule 403 objections, her assertion here that the probative value of Exhibit 7392, and Dr. Ruggieri's discussion of it, is substantially outweighed by its prejudicial nature is without basis in fact or law. More importantly, Plaintiff makes no attempt to argue a basis for their objection, but simply tack it on the end of their objection without explanation. While Defendants should not be forced to tilt at windmills, and guess as to the nature of Plaintiff's objection, it is worth noting that under any imaginable circumstance the instant 403 objection is misplaced. An FDA official's explanation of its analysis of adverse event reports is highly relevant to the instant case, and Plaintiff is correct that the content of the e-mail is prejudicial, in the sense that it is adverse to her. It is not, however, unfairly prejudicial as required by Rule 403.

20:14 Plaintiff similarly objects to Dr. Ruggieri's analysis of the July 2008 Joint Advisory Committee Meeting on AEDs and Suicidality. Dr. Ruggieri offers the opinion that the FDA's discussion of the high background incidence of suicidality in patients taking AEDs render

post-marketing data unsuitable for an analysis of the risks and benefits associated with the medicines. Plaintiff objects that Dr. Ruggieri's analysis is cumulative of that of Dr. Arrowsmith, that it lacks foundation, that there "is no evidence that the FDA concluded the postmarketing data . . . was unreliable," that Dr. Ruggieri misstates Plaintiff's reliance on post-marketing data, and that its probative value is outweighed by its prejudicial nature.

Once again, Plaintiff offers little or no basis for her objections. Importantly, Plaintiff does not explain how, even if Dr. Ruggieri's opinions are cumulative to some extent with those of another witness, why exclusion under 403 is justified. Plaintiff cannot simply contest the introduction of evidence on Rule 403 grounds without providing some explanation for their rationale. As was the case with Dr. Weiss-Smith, Dr. Arrowsmith and Dr. Ruggieri possess entirely different skill sets. While they do at times employ the same underlying facts and data, Dr. Arrowsmith serves as a general regulatory expert, while Dr. Ruggieri is a pharmacovigilance expert specializing in company practices. As a result, their opinions—arrived at by different routes—cannot be said to be cumulative.

Plaintiff's foundation objections are equally misplaced. Dr. Ruggieri's list of materials relied on clearly include information from the July 10, 2008, Joint Advisory Committee's meetings, including a transcript of the meeting in which the committee's decision making process is amply discussed. In fact, Dr. Ruggieri quotes from relevant statements by FDA officials, including Dr. Russell Katz, on which his opinions are based. Plaintiff's counsels' bald assertions that no reliable evidence exists to support Dr. Ruggieri's opinions cannot stand in the face of the obviously contradictory statements by the FDA. While Plaintiff may ultimately contest the weight of evidence showing "that the FDA concluded the postmarketing adverse event reports were unreliable," cross-examination of Dr. Ruggieri is the proper place to raise such issues.

22:6

Plaintiff's sole objection to this portion of Dr. Ruggieri's testimony is that his analysis of Pfizer's June 2006 submission of possibly suicide-related adverse event reports to the FDA is cumulative of the analysis of Dr. Arrowsmith. Even assuming Dr. Ruggieri's analysis is cumulative, Plaintiff has not and cannot argue that Rule 403 is violated in this instance. Both Drs. Ruggieri and Arrowsmith of course base their opinions in part on Pfizer's June 2006 submission to the FDA; to suggest that it is somehow violative of Rule 403 for them to do so is simply absurd. Indeed, Plaintiff's objection is the equivalent of suggesting that only one of Plaintiff's experts can base his opinion that Neurontin caused Mr. Smith's suicide on the FDA's 2008 Alert regarding AEDs. If that is the case, Defendants

respectfully suggest Plaintiff determine which of her experts will rely on the alert, and strike the testimony of the remainder.

23:5

Plaintiff objects to Dr. Ruggieri's discussion of various iterations of FDA-approved Neurontin labeling and whether it adequately conveyed necessary information to prescribers regarding the risks and benefits of suicide. Plaintiff asserts without any explanation that Dr. Ruggieri's testimony is "cumulative" of Dr. Arrowsmith-Lowe's testimony. Presumably, the basis for Plaintiff's objections is Rule 403, which allows the suppression of evidence if its probative value would be substantially outweighed by, among other things, the needless presentation of cumulative evidence."

Assuming for the sake of argument that Dr. Ruggieri's testimony is cumulative, Plaintiff cannot simply set forth a Rule 403 argument without explaining how its cumulative nature "substantially outweighs" its probative value. Absent a legitimate, grounded objection, Defendants should be free to set forth their defense in the manner they see fit. In way of additional response to the instant objection, Defendants additionally incorporate their prior response to Plaintiff's objection regarding Page 23, Line 5 of Dr. Ruggieri's testimony.

25:4

Plaintiff objects to Dr. Ruggieri's criticisms of Dr. Blume's aggregation of a number of different adverse events under the category "Psychobiologic Adverse Events." Plaintiff objects on the grounds of foundation, and assert that Defendants themselves use the term "psychobiologic." Plaintiff misunderstands, however, the basis of Dr. Ruggieri's criticisms. His criticisms in the quoted section pertain to Dr. Blume's baseless aggregation of unrelated adverse events. Dr. Ruggieri clearly states that his criticism arises because "there is no explanation or medical basis provided in the Blume report of any medical or physiological semantic relationship between this aggregate concept and the concept of suicidality." Indeed, Dr. Blume does not explain her rationale for aggregating the many adverse events listed together in her report as "psychobiologic." Nor does she endeavor to define the term "psychobiologic" in her statement. Plaintiff asserts that Dr. Ruggieri lacks foundation to make such criticisms. However, during his February 14, 2009 deposition from approximately page 355 to page 385, Dr. Ruggieri explains his basis for his criticism at length. Defendants will not endeavor to explain the basis for Dr. Ruggieri's opinions here; if Plaintiff doubts the foundation of his opinion, they should raise the issue on cross examination.

Plaintiff also objects to Dr. Ruggieri's criticisms of Dr. Blume's

qualifications to make such a determination, and point out that Dr. Ruggieri does not point to any scientific or regulatory source that establishes that she must be a medical doctor to render such an opinion. Again, Plaintiff misreads Dr. Ruggieri's statement. In fact, he generally criticizes her lack of any credential that would render her qualified to group disparate medical conditions or events under the single term "psychobiologic." Plaintiff also seeks to confuse the matter by asserting that because Dr. Blume has "done this exact task innumerable times" that that alone provides her opinions with weight. In fact, as Dr. Ruggieri points out in his December 20, 2007 expert report, Dr. Blume acknowledged on pages 225-229 of her November 12, 2007, deposition that she does not possess medical or psychiatric expertise with which to evaluate the content of individual case reports.

Again, Plaintiff's objections go to the weight, not the admissibility, of Dr. Ruggieri's testimony. Dr. Blume's and Dr. Ruggieri's respective opinions about aggregating so-called psychobiologic functions are matters for the jury to consider. It should be allowed to do so having heard Dr. Blume's opinions, and Dr. Ruggieri's criticisms, including those related to Dr. Blume's qualifications. At most, however, Defendants respectfully assert that Dr. Ruggieri's criticisms of Dr. Blume's qualifications should be stricken, but that he still be allowed to discuss his opinions of her aggregation of "psychobiologic functions."

Slide 12

Finally, Plaintiff objects to Dr. Ruggieri's use of Slide 12, which is a demonstrative of an email from an FDA official to Dr. Ruggieri which is labeled as Defense Exhibit 7392. Defendants incorporate by reference the discussion above of Dr. Ruggieri's analysis of Exhibit 7392.

Dated: May 13, 2010

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this the 13th day of May 2010, I electronically filed the foregoing document with the Clerk of the Court, United States District Court for the Middle District of Tennessee, using the CM/ECF system. True and correct copies of the foregoing documents are being served via the Court's CM/ECF system on the following:

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